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10/570,554	12/07/2006	Willem Broekaert	1187-44	5372

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,554	BROEKAERT ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-31* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 24-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *102306*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claim(s) 2-5, 7-8, 12-14 and 20-22, drawn to a method comprising increasing expression, activities or levels in a plant of an *Arabidopsis thaliana* CDK;B1;2 plant B-type CDK protein, in the reply filed on October 30, 2009 is acknowledged. Claim 1 is a linking claim.

The traversal is on the ground(s) that Groups I-VI comprise the common features of B-type CDKs

The traversal is found persuasive with respect to Groups I-VI, and these groups are rejoined.

The requirement is still deemed proper with respect to groups VII-XXIII and is therefore made FINAL.

Claims 16-19 and 24-31 are withdrawn from consideration as being directed to nonelected inventions.

Specification

The disclosure is objected to because of the following informalities: the disclosure does not comply with 37 CFR 1.182, which requires that reference be made to a sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. In the instant case reference to the sequences depicted in Figure 7 is not made by the use of sequence identifiers. Appropriate correction is required.

Claim Objections

Claims 1-15 and 20-22 are objected to because of the following informalities: the claims do not begin with an article. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: claim 5 recites "according to any claim 3", yet there is only one claim 3. Appropriate correction is required.

Claim 20 is objected to because of the following informalities: the disclosure does not comply with 37 CFR 1.182, which requires that reference be made to a sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. In the instant case reference to the nucleic acid in part (b) of claim 20 is not made by the use of sequence identifiers. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and claim 3-6 and 9-15 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is directed to a method comprising increasing expression in a plant of a nucleic acid encoding a B-type CDK protein and/or

increasing activity and/or levels in a plant of a B-type CDK protein, but the claim recites no positive method steps by which the increase may be effected.

Claim 21, and claim 22 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claim 22 is directed to a transgenic plant characterized in that said plant has increased expression of a B-type CDK nucleic acid and/or increased activity and/or levels in a plant of a B-type CDK protein relative to corresponding wild type plants, but the claim recites no actual elements essential to the increased expression and/or activity and/or levels of a B-type CDK nucleic acid or protein that characterize the plant.

Claim 1, and claim 3-6 and 9-15 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "increasing", which is a relative term that lacks a comparative basis.

Claim 4, and claim 10 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is indefinite in the recitation of "the nucleic acid sequence", which limitation lacks antecedent basis.

Claim 6, and claims 9 and 15 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is indefinite in the recitation of "wherein said B-type CDK is a class 2 B-type CDK", because claim 6 depends from claim 5, which claim limits the B-type CDK to class 1 B-type CDKs.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-9 are indefinite in the recitation of "is as represented by", because it is unclear in what way the sequence identifiers are representative of the nucleic acids and proteins.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is indefinite in the recitation of "said CDK B2;2", because claim 12 depends from claim 5, which claim limits the B-type CDK to class 1 B-type CDKs, and because there is no antecedent basis for "said CDK B2;2" in claim 12.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is indefinite in the recitation of a B-type CDK "gene/nucleic" because "gene/nucleic" is not known in the art or defined in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-9, 11-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods and plants that require B-type CDK nucleic acids or proteins derived from plant, algal or fungal sources.

The specification describes B-type CDK nucleic acids derived from plant sources (pages 5-6 Table 1). The specification does not describe any B-type CDK nucleic acid or protein derived from algal or fungal sources.

The Federal Circuit has clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is

set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002)

In the instant case Applicant has not described a representative number of species falling within the scope of the genus of B-type CDK nucleic acids and proteins required to practice the claimed methods, which genus encompasses numerous undisclosed, uncharacterized and unknown B-type CDK nucleic acids and proteins that are derived from algal or fungal sources, nor the structural features unique to the genus that constitute a substantial portion of the genus.

Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7-10 are directed to methods that require B-type CDK nucleic acids or proteins that are variant nucleic acids or variant proteins including functional portions, hybridsing sequences, alternative splice variants, allelic variants, homologues, derivatives and active fragments, and mutants.

The specification does not describe B-type CDK nucleic acids or proteins that are variant nucleic acids or variant proteins and that are functional portions, alternative splice variants, allelic variants, homologues, derivatives and active fragments, and mutants.

The Federal Circuit has clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002)

In the instant case Applicant has not described a representative number of species falling within the scope of the genus of B-type CDK nucleic acids or proteins that are variant nucleic acids or variant proteins required to practice the claimed methods, which genus encompasses numerous undisclosed, uncharacterized and unknown B-type CDK nucleic acids or proteins that

are variant nucleic acids or variant proteins and that are functional portions, alternative splice variants, allelic variants, homologues, derivatives and active fragments, and mutants, nor the structural features unique to the genus that constitute a substantial portion of the genus.

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 is directed to a method that employs a beta expansin promoter. Claim 12 is directed to a method that employs a GOS2 promoter.

The specification describes a single beta expansin promoter, the nucleotide sequence of SEQ ID NO:14 obtained from *Oryza sativa* (page 31; sequence listing). The specification also describes a single GOS2 promoter, the nucleotide sequence of SEQ ID NO:15 obtained from obtained from *Oryza sativa* (page 31; sequence listing). The specification does not describe other beta expasin promoters, or other GOS2 promoters.

The Federal Circuit has clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also

affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002)

In the instant case Applicant has not described a representative number of species falling within the scope of the genus of promoter polynucleotides required to practice the claimed methods, which genus encompasses numerous undisclosed, uncharacterized and unknown polynucleotides of unspecified structure that are designated "beta expansin promoter" or "GOS 2 promoter", nor the structural features unique to the genus that constitute a substantial portion of the genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 10-14, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by INZE D. et al. (WO 98/41642, published September 24, 1998).

The claims are drawn to a method for improving plant growth characteristics selected from one or more of increased yield, increased growth rate and modified architecture, said method comprising increasing expression in a plant of a nucleic acid encoding a B-type CDK protein and/or increasing activity and/or levels in a plant of a B-type CDK protein, including a method wherein said increasing expression is effected by introducing and expressing in a plant a class 1 B-type CDK nucleic acid derived from *Arabidopsis thaliana* wherein said class 1 B-type CDK nucleic acid is a CDK B1;1 nucleic acid as represented by SEQ ID NO: 1 or by a portion thereof, or by a nucleic acid sequence capable of hybridising therewith and wherein the CDK B1;1 protein is represented by SEQ ID NO:2 or a homologue, derivative or active fragment thereof, and including a method wherein said increasing expression is effected by introducing and expressing in a plant a B-type CDK nucleic acid derived from *Arabidopsis thaliana* wherein said B-type CDK is a mutant variant. The claims are also drawn to said methods wherein expression of the B-type CDK is driven by a promoter active in young, expanding tissue or a constitutive promoter. The claims are additionally drawn to said methods wherein the intended use is for specific modifications of architecture. The claims are further drawn to a transgenic plant having specific improved growth characteristics and characterized as having increased expression of a nucleic acid encoding a B-type CDK protein and/or increased activity and/or levels in a plant of a B-type CDK protein.

INZE D. et al. teach a method comprising increasing expression in a plant of a nucleic acid encoding a B-type CDK protein and/or increasing activity and/or levels in a plant of a B-

type CDK protein wherein said increasing expression is effected by introducing and expressing in a plant a CDC2bAt nucleic acid (pages 38-40). The CDC2bAt nucleic acid is a class 1 B-type CDK nucleic acid derived from *Arabidopsis thaliana* wherein said class 1 B-type CDK nucleic acid is a CDK B1;1 nucleic acid as represented by SEQ ID NO: 1 or by a portion thereof, or by a nucleic acid sequence capable of hybridising therewith, and wherein the CDK B1;1 protein is represented by SEQ ID NO:2 or a homologue, derivative or active fragment thereof, i.e. see Table 1 at page 611 of Joubès J. et al. CDK-related protein kinases in plants. Plant Mol Biol. 2000 Aug;43(5-6):607-20. Review. INZE D. et al. also teach a method wherein said increasing expression is effected by introducing and expressing in a plant a B-type CDK nucleic acid derived from *Arabidopsis thaliana* wherein said B-type CDK is a mutant variant, i.e. Cdc2bAt-DN (pages 38-40). INZE D. et al. additionally teach a method wherein expression of the B-type CDK is driven by a triple-op promoter (Top3) promoter (pages 38-40). The triple-op promoter (Top3) promoter is a constitutive promoter because it is constructed from the constitutive CaMV 35S promoter. i.e see Gatz C. et al. Stringent repression and homogeneous de-repression by tetracycline of a modified CaMV 35S promoter in intact transgenic tobacco plants. Plant J. 1992 May;2(3):397-404. The triple-op promoter (Top3) promoter would be active in young, expanding tissue because it is a constitutive promoter, i.e. it is active in all tissues.

While INZE D. et al. do not teach the specific intended uses recited in claim 1 or claim 14, INZE D. et al. need not teach these intended uses in order to anticipate the rejected claims because they are recited in the preamble of claim 1 and are thus not limiting. Additionally, while INZE D. et al. are silent with respect to the specific improved growth characteristics recited in claim 21, INZE D. et al. need not explicitly teach these characteristics in order to anticipate the

rejected claims because these characteristics are inherent to the transgenic plants taught by INZE D. et al., since it is the increased expression of a nucleic acid encoding a B-type CDK protein and/or increased activity and/or levels in a plant of a B-type CDK protein that causes the plants to exhibit these characteristics.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Lee J. et al. (Cell cycle function of a rice B2-type cyclin interacting with a B-type cyclin-dependent kinase. Plant J. 2003 May;34(4):417-25).

The claim is drawn to a transgenic plant of claim 21 that is a monocotyledonous plant.

Lee J. et al. teach a transgenic monocotyledonous plant (rice) transformed with a B-type CDK nucleic acid (page 421 column 1 last paragraph). While Lee J. et al. are silent with respect to the specific improved growth characteristics recited in claim 21, Lee J. et al. need not explicitly teach these characteristics in order to anticipate the rejected claim, because these characteristics are inherent to the transgenic plants taught by Lee J. et al., since it is the increased expression of a nucleic acid encoding a B-type CDK protein and/or increased activity and/or levels in a plant of a B-type CDK protein that causes the plants to exhibit these characteristics.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 8-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over INZE D. et al. (WO 98/41642, published September 24, 1998) in view of Boudolf V. et al. (Identification of novel cyclin-dependent kinases interacting with the CKS1 protein of Arabidopsis. J Exp Bot. 2001 Jun;52(359):1381-2).

The claims are drawn to the method of claim 5 or claim 6 wherein the B-type CDK is a CDK B1;2 or CDK B2;2 as represented by SEQ ID NO: 3 or 5 or by a portion thereof, or by a nucleic acid sequence capable of hybridising therewith, and as represented by SEQ ID NO: 4 or 6 or a homologue, derivative or active fragment thereof, and to plants obtainable by the method.

The teachings of INZE D. et al. are set forth above.

INZE D. et al. do not teach a B-type CDK is a CDK B1;2 or CDK B2;2 as represented by SEQ ID NO: 3 or 5 or by a portion thereof, or by a nucleic acid sequence capable of hybridising therewith, and as represented by SEQ ID NO: 4 or 6 or a homologue, derivative or active fragment thereof, or a transgenic monocotyledonous plant.

Boudolf V. et al. teach a B-type CDK is a CDK B1;2 and CDK B2;2 as represented by SEQ ID NO: 3 or 5 or by a portion thereof, or by a nucleic acid sequence capable of hybridising therewith, and as represented by SEQ ID NO: 4 or 6 or a homologue, derivative or active fragment thereof (page 1382 Table 1).

Given the teachings of INZE D. et al. that the expression in a plant of a nucleic acid encoding a B-type CDK protein and/or the activity and/or the levels in a plant of a B-type CDK protein can be increased by transforming a plant with a CDC2bAt nucleic acid encoding a B-type CDK, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute another nucleic acid encoding another B-type CDK for the

CDC2bAt nucleic acid used by INZE D. et al., such as the nucleic acids encoding the B-type CDKs CDK B1;2 and CDK B2;2 taught by Boudolf V. et al. Such a substitution would have been an obvious modification of design parameters, given that transformation methods in general, the transformation of plants with the B-type CDK CDC2bAt nucleic acid, and the availability of other B-type CDK nucleic acids were known to and within the abilities one of ordinary skill in the art at the time of filing. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC